Docket Number: EPA-HQ-OPP-2012-0683
www.regulations.gov

Ammonium Bromide
Interim Registration Review Decision
Case Number 5002

March 2020

Approved by:_____
Anita Pease
Director
Antimicrobials Division

Date: _____3/6/2020_____

Docket Number: EPA-HQ-OPP-2012-0683
www.regulations.gov

Ammonium Bromide Registration Review Team

Human Health and Environmental Fate and Effects

Diana Hsieh
Judy Facey
Laura Parsons
Melissa Panger

Risk Management

Stephen Savage
Demson Fuller
Rick Fehir

Table of Contents

I. Introduction

This document is the Environmental Protection Agency's (EPA or the Agency) Interim Registration Review Decision (ID) for ammonium bromide (PC Code 000352; case 5002) and is being issued pursuant to 40 CFR 155.56 and 155.58. A registration review decision is the Agency's determination whether a pesticide meets, or does not meet, the standard for registration in the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The Agency may issue, when it determines it to be appropriate, an interim registration review decision before completing a registration review. Among other things, the interim registration review decision may: 1) require new risk mitigation measures; 2) impose interim risk mitigation measures; 3) identify additional data or other information required to complete the review; and 4) include schedules for submitting the required data, conducting the new risk assessment, and completing the registration review. For further information on ammonium bromide, additional documents can be found in the Agency's public docket (EPA-HQ-OPP-2012-0683) at www.regulations.gov.

FIFRA, as amended by the Food Quality Protection Act (FQPA) of 1996, mandated the continuous review of existing pesticides. All pesticides distributed or sold in the United States generally must be registered by the Agency based on scientific data showing that they will not cause unreasonable risks to human health or to the environment when used as directed on product labeling. The registration review program is intended to make sure that, as the ability to assess and reduce risk evolves and as policies and practices change, all registered pesticides continue to meet the statutory standard of no unreasonable adverse effects. Changes in science, public policy, and pesticide use practices will occur over time. Through the registration review program, the Agency periodically re-evaluates pesticides to make sure that as these changes occur, products in the marketplace can continue to be used safely. Information on this program is provided at http://www.epa.gov/pesticide-reevaluation. In 2006, the Agency implemented the registration review program pursuant to FIFRA section 3(g) and will review each registered pesticide every 15 years to determine whether it continues to meet the FIFRA standard for registration.

The Agency is issuing an interim registration review decision for ammonium bromide so that it can move forward with aspects of the registration review that are complete. The Agency has evaluated risks to listed species and is making a "no effect" finding for listed species and designated critical habitat and has therefore concluded that consultation with the Fish and Wildlife Service and the National Marine Fisheries Service under the Endangered Species Act (ESA) section 7(a)(2) is not required. The Agency will complete endocrine screening for ammonium bromide, pursuant to Federal Food, Drug, and Cosmetic Act (FFDCA) Section 408(p), before completing this registration review. See the Ammonium Bromide Proposed Interim Registration Review Decision, Appendices A and B respectively, for additional information about the endangered species assessment and the endocrine screening for the registration review of ammonium bromide.[1]

This document is organized in five sections: the *Introduction*, which includes this summary; *Use and Usage*, which describes how and why ammonium bromide is used and summarizes data on

[1] https://www.regulations.gov/document?D=EPA-HQ-OPP-2012-0683-0009

its use; *Scientific Assessments*, which summarizes the Agency's risk assessments, updates or revisions to previous risk assessments, and provides broader context with a discussion of risk characterization; the *Interim Registration Review Decision*, which describes the regulatory rationale for the Agency's interim registration review decision; and, lastly, the *Next Steps and Timeline* for completion of this registration review.

A. Updates Since the Proposed Interim Registration Review Decision was Issued

The Agency did not receive any public comments concerning the Draft Risk Assessment or the Proposed Interim Decision, thus this ID does not have any changes to what was proposed. The Agency will not require risk mitigation for ammonium bromide at this time.

Summary of Ammonium Bromide Registration Review

Pursuant to 40 CFR 155.50, The Agency formally initiated registration review for ammonium bromide with the opening of the registration review docket for the case. The following highlights significant events that have occurred during the registration review of ammonium bromide and can be found in The Agency's public docket, EPA-HQ-OPP-2012-0683, accessed at www.regulations.gov:

- September 2012 - Publication of the *Ammonium Bromide Summary Document: Registration Review: Initial Docket* for a 60-day public comment period. The Summary Document included the Preliminary Work Plan (PWP) and was accompanied by the: *Ammonium Bromide: Human Health Registration Review Scoping Document* and *Product Chemistry, Environmental Fate, and Ecological Effects Scoping Document in Support of Registration Review of Ammonium Bromide*.

- February 2013 - Publication of the *Ammonium Bromide Registration Review: Final Work Plan* (FWP). The Agency received one comment on the Summary Document. The comment did not change the data needs, planned risk assessments, or the timeline for the registration review case; thus, the FWP did not modify the PWP.

- December 2016 - A Generic Data Call-In (GDCI) for ammonium bromide was issued (GDCI-000352-1436). The GDCI required the following data: particle size: fiber length, and diameter distribution (Guideline Number 830.7520), 90-day inhalation toxicity (870.3465) and inhalation exposure indoor (875.1400). The GDCI was satisfied since the Agency determined that all data requirements were either waived or were no longer required to complete the risk assessment.

- November 2019 - Publication of the *Registration Review Draft Risk Assessment for Ammonium Bromide* (DRA) and the *Ammonium Bromide Proposed Interim Registration Review Decision* (PID) for a 60-day public comment period. No public comments were submitted concerning the DRA or PID.

- February 2020 - The Agency has completed the *Ammonium Bromide Interim Registration Review Decision* and will announce its availability in the Federal Register and place it in docket EPA-HQ-OPP-2012-0683.

II. Use and Usage

The ammonium bromide case contains one active ingredient (AI) (PC Code 000352). The first product containing ammonium bromide was registered as a pesticide in the United States in January 1999 for use as a bactericide and slimicide in recirculating cooling water systems and pulp and paper mills. Currently, there are three products formulated with ammonium bromide as an AI: registration numbers (Reg. Nos.) 8622-59, 8622-64 and 8622-75. Two of these products (Reg. Nos. 8622-59 and 8622-75) are manufacturing use products (MUPs) that are used to formulate end use products (EUPs), and the third product (Reg. No. 8622-64) is an EUP. The MUPs are solid concentrates that contain 99% AI, and the EUP product is a liquid concentrate that contains 35% AI.

Pesticides formulated with ammonium bromide are used as bactericides, slimicides, and algaecides to control bacteria, fungi, and algae in recirculating cooling water systems and pulp and paper mills. Ammonium bromide formulated products are not intended for homeowner use or for use in or around residences. Ammonium bromide is used in a mixture with an oxidant, such as sodium hypochlorite (12.5%) or chlorine gas (99.9%), in a specially designed reactor to produce bromide activated monochloramine on site. The monochloramine solution is then pumped into the systems being treated. The treatment can be administered using the slug, intermediate or continuous feed methods.

III. Scientific Assessments

A. Human Health Risk

A summary of the Agency's human health risk assessment is presented below in support of the registration review of ammonium bromide. The Agency used the most current science policies and risk assessment methodologies to prepare a risk assessment in support of the registration review of ammonium bromide. For a detailed discussion of all aspects of the human health assessment, see the Ammonium Bromide Draft Risk Assessment located in the public docket at EPA-HQ-OPP-2012-0683.

1. Summary of Human Health Risks and Risk Characterization

A summary of the Agency's human health risk assessment is presented in the PID. The Agency has concluded there are no dietary, residential, aggregate, or cumulative risks of concern for ammonium bromide.

Since the PID, there have been no changes to the Agency's previous human health risk conclusions. For additional details, see the Registration Review Draft Risk Assessment for Ammonium Bromide dated September 2019 and the Proposed Interim Registration Review

Decision dated November 2019. Both of these documents can be found in the EPA's public docket EPA-HQ-OPP-2012-0683 at http://www.regulations.gov.

2. Human Health Data Gaps

The data were sufficient to complete a risk assessment for the ammonium bromide case. Therefore, no data gaps were found, and no additional human health studies are required for the registration review of ammonium bromide.

3. Human Incidents

A search of the Agency's Incident Data System (IDS) on January 10, 2020, did not identify any incidents. The Agency will continue to monitor the incident information. Additional analyses will be conducted if ongoing human incident monitoring indicates a concern.

4. Dietary Exposure/Tolerances

Since the exposure of ammonium bromide to dietary food and water is expected to be negligible, the Agency has determined that a dietary risk assessment is not needed for registration review. No tolerances or exemptions from the requirement of a tolerance have been established for ammonium bromide under FFDCA Section 408. However, the Food and Drug Administration (FDA) has issued Food Contact notifications (FCN) for ammonium bromide when used as a 35% solution. FCN numbers 384, 730, and 959 allow specific manufacturers and its customers to use ammonium bromide as a slimicide or additive for finished coating formulations. See **Table 1 - Summary of FDA Food Contact Notifications (FCN's)** for further details. Other than the issued FCNs, there are no other tolerances or clearances for ammonium bromide.

Table 1 - Summary of FDA Food Contact Notifications (FCN's)

FCN No.	Company	Use	Maximum Residue Level
384	ICL-IP America Inc. (formerly AmeriBrom Inc.)	For use as a slimicide in the production of paper and paperboard.	For use at levels not to exceed 0.14 gallons per ton of dry weight fiber. The other component of this antimicrobial system is sodium hypochlorite.
730	AmeriBrom Inc.	For use as an antimicrobial agent for finished coating formulations for paper and for additives to the finished coating formulations including starch slurries, sizing solutions, pigments, fillers, and binders used in the manufacture of paper and paperboard.	Not to exceed 0.0085 gallons (0.032 liter) per metric ton of coating formulation.

959	AmeriBrom Inc.	For use as a component of a slimicide in the production of paper and paperboard.	Not to exceed 0.2 gallons per metric ton of dry weight fiber.

B. Environmental Risk

A summary of the Agency's environmental risk assessment is presented below in support of the registration review of ammonium bromide. The Agency used the most current science policies and risk assessment methodologies to prepare a risk assessment in support of the registration review of ammonium bromide. For a detailed discussion of all aspects of the ecological assessment, see the *Registration Review Draft Risk Assessment for Ammonium bromide* located in the public docket at EPA-HQ-OPP-2012-0683 at www.regulations.gov.

1. Summary of Ecological Risks and Risk Characterization

Since the PID, there have been no changes to the Agency's previous ecological risk conclusions that risks are not of concern due to lack of exposure. The Agency has determined that no pollinator exposure and effects data are necessary to make a final registration review decision for ammonium bromide. For additional details, see the Registration Review Draft Risk Assessment for Ammonium Bromide dated September 2019 and the Proposed Interim Registration Review Decision dated November 2019. Both of these documents can be found in the EPA's public docket EPA-HQ-OPP-2012-0683 at http://www.regulations.gov.

2. Ecological Incidents

A search of the Agency's Incident Data System (IDS) on January 22, 2020 did not identify any ecological incidents from the use of ammonium bromide. Based on the absence of ammonium bromide incidents reported, there does not appear to be a concern for ammonium bromide at this time. The Agency will continue to monitor incident data and if a concern is triggered, additional analysis will be conducted.

3. Ecological and Environmental Fate Data Gaps

The data were sufficient to complete a risk assessment for the ammonium bromide case. Therefore, no data gaps were found and no additional ecotoxicity studies are required for the registration review of ammonium bromide.

IV. Interim Registration Review Decision

A. Risk Mitigation and Regulatory Rationale

In the *Registration Review Draft Risk Assessment for Ammonium bromide*, the Agency determined that there are no human health or ecological risks of concern for the uses of ammonium bromide. Therefore, risk mitigation measures are not needed at this time.

V. Next Steps and Timeline

A. Interim Registration Review Decision

In accordance with 40 CFR 155.56 and 155.58, the Agency is issuing the *Ammonium bromide Interim Registration Review Decision*. A Federal Register Notice will announce the availability of this Interim Registration Review Decision. With the exception of the Endocrine Disruptor Screening Program (EDSP) component of this case, the agency has made the following Interim Registration Review Decisions: (1) no additional data are required to be called in at this time, and (2) no changes to the affected registrations or their labeling are needed at this time.

In this ID, the Agency is making no human health or environmental safety findings associated with the EDSP screening of ammonium bromide. The agency has made a "no effect" determination for the registered uses of ammonium bromide under the ESA. The agency's final registration review decision for ammonium bromide will be dependent upon the result of the agency's EDSP FFDCA section 408(p) determination. See the Proposed Interim Registration Review Decision for ammonium bromide Appendices A and B, respectively, for additional information about the endangered species assessment and the endocrine screening for the registration review of ammonium bromide.

B. Implementation of Mitigation Measures

This Interim Registration Review Decision does not include any risk mitigation measures for ammonium bromide.